



**[BILLING CODE: 6750-01S]**

**FEDERAL TRADE COMMISSION**

**[File No. 161 0084]**

**Abbott Laboratories and Alere Inc.; Analysis to Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

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**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

**DATES:** Comments must be received on or before October 30, 2017

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "In the Matter of Abbott Laboratories and Alere Inc., File No. 161-0084" on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/abbottalereconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write "In the Matter of Abbott Laboratories and Alere Inc., File No. 161-0084" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC

20024.

**FOR FURTHER INFORMATION CONTACT:** Aylin M. Skroejer, (202-326-2459), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for September 28, 2017), on the World Wide Web, at <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 30, 2017. Write “In the Matter of Abbott Laboratories and Alere Inc., File No. 161-0084” on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <https://www.ftc.gov/policy/public-comments>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/abbottalereconsent> by following the instructions on the

web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that website.

If you prefer to file your comment on paper, write “In the Matter of Abbott Laboratories and Alere Inc., File No. 161-0084” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC Website at <https://www.ftc.gov>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential” – as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2) – including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC Website – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 30, 2017. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

## **Analysis of Agreement Containing Consent Orders to Aid Public Comment**

### **INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Abbott Laboratories (“Abbott”) and Alere Inc. (“Alere”) designed to remedy the anticompetitive effects resulting from Abbott’s proposed acquisition of Alere. The proposed Decision and Order (“Order”) contained in the Consent Agreement requires the parties to divest all rights and assets related to

Alere's point-of-care blood gas testing business to Siemens Aktiengesellschaft ("Siemens"), and all rights and assets related to Alere's point-of-care cardiac marker testing business to Quidel Corporation ("Quidel").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Under the terms of the Amendment to Agreement and Plan of Merger signed on April 13, 2017, which amends the Agreement and Plan of Merger signed on January 30, 2016, Abbott will acquire Alere in a transaction valued at approximately \$8.3 billion, which includes Abbott's assumption of \$3.0 billion in debt (the "Acquisition"). The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for point-of-care blood gas testing systems and point-of-care cardiac marker testing systems. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

## **THE PARTIES**

Abbott, headquartered in Abbott Park, Illinois, is a global healthcare company with three business units in the United States: diagnostic, nutritional, and vascular. Its diagnostic testing division provides an expansive portfolio of instruments, tests, software, and training to hospitals, laboratories, blood banks, and physician offices.

Alere, headquartered in Waltham, Massachusetts, is a global leader in rapid diagnostic testing. Alere provides diagnostic equipment, consumables, and patient self-management tools for cardiometabolic disease, infectious disease, and toxicology.

## **THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS**

### **I. Point-of-Care Blood Gas Testing Systems**

Point-of-care blood gas testing systems are small, portable medical instruments that measure a patient's blood pH, oxygen, carbon dioxide, and electrolyte levels to assess lung and kidney function, as well as whether an acute patient requires oxygen or other urgent treatment. They provide results in less than five minutes at a patient's bedside or other acute care settings where fast turnaround time is critical, and rely on single-use, disposable test cartridges. Abbott and Alere offer the only handheld point-of-care blood gas testing devices, and other firms offer portable point-of-care models that range up to ten pounds in weight. Hospitals pay a substantial premium for the convenience of point-of-care blood gas testing equipment over the closest alternative, using larger benchtop analyzers that employ multi-use packs of reagents and are typically located in a hospital laboratory or other centralized location for analysis. The vast majority of customers would not switch to benchtop blood gas testing systems in response to a small but significant increase in the price of point-of-care blood gas testing systems.

Abbott and Alere are each other's closest competitors and the only significant suppliers in the U.S. market for point-of-care blood gas testing systems, accounting for 82% and 15% of 2016 sales, respectively. While IDEXX Laboratories, Inc. and LifeHealth LLC offer single-use, portable (but not handheld) systems, they are more distant competitors to Abbott and Alere and maintain fringe positions in the market.

## **II. Point-of-Care Cardiac Marker Testing Systems**

Point-of-care cardiac marker testing systems are small, portable medical instruments that measure specific proteins released into the blood to assess whether a patient experiencing chest pains is having a myocardial infarction or congestive heart failure. They allow for quick initial diagnoses at a patient's bedside, which is critical because the time between a cardiac event and treatment increases the likelihood the patient will suffer permanent loss of heart muscle. The convenience of point-of-care cardiac marker testing systems differentiates them from larger benchtop models that can only be located in a hospital laboratory or some other central area of larger emergency departments. A small but significant increase in the price of point-of-care cardiac marker testing systems would not cause customers to switch to benchtop cardiac marker testing systems.

Abbott and Alere are the only significant suppliers of point-of-care cardiac marker testing systems, accounting for approximately 87% and 13%, respectively, of the 2016 U.S. market. Abbott offers point-of-care cardiac marker testing on a handheld analyzer, and Alere on a two-pound portable analyzer. The next closest competitor to the parties is Response Biomedical, which offers a more complex technology and accounts for only a nominal share of the market.

### **THE RELEVANT GEOGRAPHIC MARKET**

The relevant geographic market for point-of-care blood gas testing systems and point-of-care cardiac marker testing systems is the United States. These products are medical devices regulated by the U.S. Food and Drug Administration ("FDA"). Medical devices sold outside of the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

## **COMPETITIVE EFFECTS OF THE ACQUISITION**

The proposed Acquisition would likely result in significant competitive harm to consumers in the markets for point-of-care blood gas testing systems and point-of-care cardiac marker testing systems. In each relevant market, customers are able to leverage Abbott and Alere against each other to obtain better prices and improved products. By eliminating this direct and substantial head-to-head competition, the proposed Acquisition likely would allow the combined firm to exercise market power unilaterally, resulting in higher prices, reduced innovation, and less choice for consumers.

## **ENTRY CONDITIONS**

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, and establishment of a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

## **THE CONSENT AGREEMENT**

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring Alere to divest: (1) its point-of-care blood gas testing business, including its Ottawa, Canada facilities, to Siemens; and (2) its point-of-care cardiac marker testing business, including its San Diego, California facility, to Quidel. Alere must divest all assets and rights to research, develop, manufacture, market, and sell its point-of-care blood gas testing and point-of-care cardiac marker testing product lines, including all related intellectual property and other confidential business information. Further, Siemens and Quidel intend to hire



substantially all of Alere's employees whose responsibilities primarily relate to the research, development, manufacture, or sale of the relevant products. The provisions of the Consent Agreement ensure that Siemens and Quidel become independent, viable, and effective competitors in the respective markets in order to maintain the competition that currently exists.

Siemens is a global conglomerate with a healthcare division that is one of the world's largest suppliers of technology to the healthcare industry and a leader in medical imaging and laboratory diagnostics. Siemens currently supplies a benchtop blood gas testing system, and Alere's handheld system will be highly complementary to Siemens' portfolio in the United States. Siemens has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost pursuant to the proposed Acquisition.

Based in San Diego, California, Quidel develops, manufactures, and markets point-of-care diagnostic testing solutions globally. The company has expertise with immunoassay testing and currently focuses on infectious diseases, women's and general health, and gastrointestinal diseases. The acquisition of Alere's point-of-care cardiac marker testing business will complement Quidel's portfolio of rapid diagnostic testing solutions. Moreover, Quidel's chairman was co-inventor of Alere's point-of-care cardiac marker testing system, providing Quidel with additional understanding and background of the divestiture business.

The parties must accomplish the divestitures no later than thirty days after the consummation of the Proposed Acquisition. If the Commission determines that either Siemens or Quidel is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Siemens and/or Quidel and then divest the products to a Commission-approved acquirer(s) within six months of the date the Order becomes final.

The Commission has agreed to appoint a Monitor to ensure that Abbott and Alere comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Siemens and Quidel. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,  
Secretary.

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